

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant: | Denise Faustman | Confirmation No.: | 1044 |
| Serial No.: | 10/775,487 | Art Unit: | 1644 |
| Filed: | February 10, 2004 | Examiner: | Zachary S. Skelding |
| Customer No.: | 21559 | | |
| Title: | METHODS FOR DIAGNOSING AND TREATING AUTOIMMUNE DISEASE | | |

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PETITION TO WITHDRAW FINALITY UNDER 37 C.F.R. § 1.181

Applicant respectfully requests withdrawal of finality of the Office Action issued in connection with the above-referenced application on September 13, 2007.

Under M.P.E.P. § 706.07, “the invention as disclosed and claimed should be thoroughly searched in the first action and the references fully applied; and in reply to this action the applicant should amend with a view to avoiding all the grounds of rejection and objection.” This section also states that the “applicant who is seeking to define his or her invention in claims that will give him or her the patent protection to which he or she is justly entitled should receive the cooperation of the examiner to that end, and not be prematurely cut off in prosecution of his or her application.” The M.P.E.P. § 706.07(d) also states that “[i]f, on request by applicant for reconsideration, the primary examiner finds the final rejection to have been premature, he or she should withdraw the finality of the rejection.” Finally, the M.P.E.P. § 706.07(e) states “The

examiner may withdraw the rejection of finally rejected claims. If new facts or reasons are presented such as to convince the examiner that the previously rejected claims are in fact allowable or patentable in the case of reexamination, then the final rejection should be withdrawn.”

The facts of the case are as follows. On December 15, 2006, the Office issued a non-final action that included, *inter alia*, a rejection of claim 77 for lack of written description, a rejection of claims 76, 77, 79, and 80 for lack of enablement, and a rejection of claims 76, 77, 79, and 80 for anticipation by Satoh et al. (U.S. Patent No. 5,560,908) in combination with Hsu et al. (Cell 84:299-208, 1996) and by Faustman (U.S. Patent No. 6,660,487) alone. There was also an objection to the inventor’s oath/declaration and a rejection of claims 76, 77, 79, and 80 for obviousness-type double patenting over claim 9 of Faustman (U.S. Patent No. 6,660,487). In a reply filed by Applicant on June 15, 2007, Applicant fully addressed all of the rejections, including the submission of a Declaration by the inventor, Dr. Denise Faustman, which provided experimental data in support of the enablement of pending claims 76, 77, 79, and 80.

Applicant’s amendments and responses were sufficient to remove the objection to the oath/declaration, the rejections with respect to written description, and the anticipation rejections. The Office, though, issued an Office Action on September 13, 2007, and designated it Final, stating that the rejection of claims 76, 77, 79, and 80 for lack of enablement was maintained. The Office also included a new rejection of claims 76, 77, 79, and 80 for anticipation by Jacob et al. (Proc. Natl. Acad. Sci. USA 87:968-972, 1990), which the Office states was prompted by “Applicant’s submission of an information disclosure statement under 37 CFR 1.97 with the fee set forth in 37 CFR 1.17(p) on July 2, 2007” (Office Action dated September 13, 2007, p. 12).

Applicant respectfully submits that finality was premature in this case. In particular, Applicant believes that the Office has not given Applicant a “full and fair hearing...[so that] a clear issue between applicant and examiner...[can] be developed...before appeal” (M.P.E.P. § 706.07). In response to the Office’s enablement rejection, Applicant submitted the Declaration of Dr. Faustman, which included experimental data, observations, and statements of fact that support the full scope of pending claims 76, 77, 79, and 80. The Office dismissed Applicant’s data and statements, stating that “insufficient experimental details and/or insufficient data [have been] provided to understand the true significance of the statements made in [the Declaration]” (Office Action, p. 6). The Office also raised several additional questions regarding the breadth and significance of Applicant’s data and statements, namely, whether Applicant has provided sufficient guidance and direction to practice the full scope of the present invention, in particular, the *in vivo* treatment of humans having any autoimmune disease. Applicant believes that the *in vitro* data presented in the specification and in the Declaration is more than sufficient to demonstrate the enablement of present claims 76, 77, 79, and 80. Moreover, *in vivo* data is not required to show enablement, especially where “there is a reasonable correlation between the disclosed *in vitro* utility and an *in vivo* activity” (see M.P.E.P. § 2164.02, quoting *Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 USPQ 739, 747 (Fed. Cir. 1985)). Such is the case here.

Nonetheless, Applicant believes that the issue here is not related to the quantity or quality of Applicant’s data, but rather of the *significance* of Applicant’s data. Applicant believes that the data provided in the specification and the Declaration is more than sufficient to convince one of skill in the art that the full breadth of the present invention is enabled (see M.P.E.P. § 2164.05; “The evidence provided by applicant need not be conclusive but merely convincing to one skilled

in the art.”). Thus, Applicant simply seeks an opportunity to provide the Office with the information it needs to fully understand the significance of Applicant’s data. Withdrawal of finality would provide Applicant with that further opportunity. For this reason, Applicant respectfully requests withdrawal of finality of the present case.

Furthermore, Applicant should be given an opportunity to fully address the Office’s questions and to rebut the Office’s doubts about the scope of Applicant’s invention. The Office states that “the [experimental] details need to be made clear in order to properly understand the meaning of [the data presented in] Section 8 and how it fits in with the disclosure of the instant specification” (Office Action dated September 13, 2007, p. 7). Thus, the Office’s statements confirm that further discussions regarding the import of Dr. Faustman’s discoveries are warranted and should continue; Applicant should not be cut off in mid-stream. Applicant seeks an opportunity to resume these discussions.¹ Because the prosecution of an application is technically closed after the mailing of a final Office Action, the Office is given discretion with respect to the entry of claim amendments and the consideration of Applicant’s further remarks in response to the final Office Action. The Office could simply choose not to consider Applicant’s amendments and remarks made in response to the final Office Action if they were deemed insufficient to fully address the present rejections, even if such amendments and remarks were made by Applicant in a *bona fide* attempt to place the application in condition for allowance. Thus, by making the Office Action final after the filing of only one substantive response by Applicant, the Office has effectively foreclosed Applicant’s ability to adequately address all of the questions presently raised by the Office. Applicant simply seeks a further opportunity to

¹ In fact, Applicant has arranged an in person interview with the Examiner on November 19, 2007, to discuss the merits of, and to expedite prosecution of, the present application.

“define...her invention in claims that will give...her the patent protection to which...she is justly entitled...[and respectfully requests] the cooperation of the examiner to that end” (M.P.E.P. § 706.07). For this reason as well, Applicant respectfully requests that finality of the present Office Action be withdrawn.

Finally, Applicant notes that a fair opportunity to address the new rejection of claims 76, 77, 79, and 80 for anticipation by Jacob et al., which was cited by Applicant in a supplemental information disclosure statement filed on July 2, 2007, has not be provided. Applicant, in good faith and in compliance with their duty of disclosure, submitted the supplemental information disclosure statement. Applicant should not be denied a full opportunity to respond to this new ground of rejection. For this reason as well, Applicant respectfully requests withdrawal of finality of the present Office Action.

Applicant should not be prematurely cut off from prosecution while seeking the patent protection to which she is entitled. Given the fact that the present invention is directed to subject matter that has been suggested by the Office to contradict the current paradigm for treatment of autoimmune disease (see Office Action dated December 15, 2006, pp. 6-7, and Office Action dated September 13, 2007, p. 9), Applicant respectfully believes that one further opportunity to present additional arguments and evidence is warranted. Moreover, Applicant believes that further communications with the Office may resolve many of the issues raised by the Office in its analysis of the data submitted in Dr. Faustman’s Declaration.

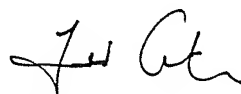
CONCLUSION

For all of these reasons, Applicant respectfully requests withdrawal of finality.

If there are any charges or any credits, kindly apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 13 November 2007



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